

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

INTERNATIONAL APPLICATION NO.
PCT/US2004/24718

INTERNATIONAL FILING DATE
July 30, 2004

PRIORITY DATE CLAIMED
August 1, 2003

TITLE OF INVENTION

Bowman-Birk Inhibitor Compositions for Treatment of Muscular Atrophy and Degenerative Muscle Disease

APPLICANT(S) FOR DO/EO/US

Sweeney et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. **EV 729462581US**

U.S. APPLICATION NO (if known, see 37 CFR 1.5) 10/566,796	INTERNATIONAL APPLICATION NO. PCT/US2004/24718	ATTORNEY'S DOCKET NUMBER PENN0870US.NP
23. Other items or information: 1) Copy of Notification of Missing Requirements; 2) Petition for Extension of Time		
The following fees have been submitted:		CALCULATIONS PTO USE
24. <input type="checkbox"/> Basic national fee \$300		\$ \$0.00
25. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). . . \$0 All other situations. \$200		\$ \$0.00
26. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). . . \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. \$100 International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. \$400 All other situations. \$500		\$ \$0.00
TOTAL OF 24, 25 and 26 =		\$ \$0.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.		
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)
- 100 =	0 /50 =	0
		x \$250.00
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$ \$130.00
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total claims	- 20 =	0
Independent claims	- 3 =	0
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00		\$ \$0.00
TOTAL OF ABOVE CALCULATIONS =		\$ \$130.00
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		\$ \$65.00
SUBTOTAL =		\$ \$65.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$ \$0.00
TOTAL NATIONAL FEE =		\$ \$65.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +		\$ \$0.00
TOTAL FEES ENCLOSED =		\$ \$575.00
		Amount to be \$
		Amount to be \$

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1619. A duplicate copy of this sheet is enclosed.
- d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Kathleen A. Tyrrell, Reg. No. 38,350

Licata & Tyrrell P.C.

66 E. Main Street

Marlton, New Jersey 08053

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Facsimile: (856) 810-1454


SIGNATURE

Kathleen A. Tyrrell

NAME

38,350

REGISTRATION NUMBER

November 9, 2006

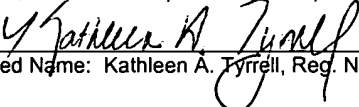
DATE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: PENN0870US.NP
Inventors: Sweeney et al.
Serial No.: 10/566,796
Filing Date: Not Yet Assigned
Examiner: Not Yet Assigned
Customer No.: 26259
Group Art Unit: Not Yet Assigned
Confirmation No.: 8993
Title: Bowman-Birk Inhibitor
Compositions for Treatment of
Muscular Atrophy and
Degenerative Muscle Disease

"Express Mail" Label No. EV729462581US
Date of Deposit November 9, 2006

I hereby certify that this paper is being deposited with the
United States Postal Service "Express Mail Post Office
to Addressee" service under 37 CFR 1.10 on the date
indicated above and is addressed to the Commissioner for Patents
Post Office, Box 1450, Box Sequence, Alexandria, VA 22313-1450

By 
Typed Name: Kathleen A. Tyrrell, Reg. No. 38,350

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS

In response to the Notification of Missing Requirements dated
June 9, 2006, a response to which is due August 9, 2006. A
Petition for a three (3) month extension of time and the requisite
fee are provided herewith. Enclosed herewith for filing is the
original Combined Declaration and Power of Attorney, executed by

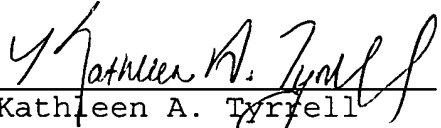
the inventor(s). An unexecuted copy of this document, attached to the above-identified specification, was filed by Express Mail No. **EV626224925US** on January 31, 2006.

Further, Applicants' attorney has carefully reviewed the application and respectfully disagrees that a Sequence Listing is required. There are no nucleotide and/or amino acid sequences disclosed in the instant application which require submission of a Sequence Listing. Reconsideration of this requirement is therefore respectfully requested.

Applicants believe this to be a complete response to the Notification of Missing Requirements.

A copy of this Notification is provided herewith.

Respectfully submitted,


Kathleen A. Tyrrell
Registration No. 38,350

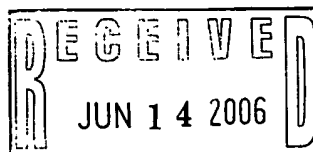
Date: November 9, 2006

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UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/566,796	Lee H. Sweeney	PENN087USNP

26259
 LICATLA & TYRRELL P.C.
 66 E. MAIN STREET
 MARLTON, NJ 08053

Docket System ☒
 Status Report ☒
 Docket Book ☒

INTERNATIONAL APPLICATION NO.	
PCT/US04/24718	
I.A. FILING DATE	PRIORITY DATE
07/30/2004	08/01/2003

CONFIRMATION NO. 8993

371 FORMALITIES LETTER



OC000000019196561

Date Mailed: 06/09/2006

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 01/31/2006
- Copy of the International Search Report filed on 01/31/2006
- Copy of IPE Report filed on 01/31/2006
- Oath or Declaration filed on 01/31/2006
- U.S. Basic National Fees filed on 01/31/2006
- Priority Documents filed on 01/31/2006
- Power of Attorney filed on 01/31/2006
- Specification filed on 01/31/2006
- Claims filed on 01/31/2006
- Abstracts filed on 01/31/2006

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
 - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c) Applicant must provide an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the application and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new

matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).

- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

BARBARA A CAMPBELL

Telephone: (703) 308-9140 EXT 217

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/566,796	PCT/US04/24718	PENN087USNP